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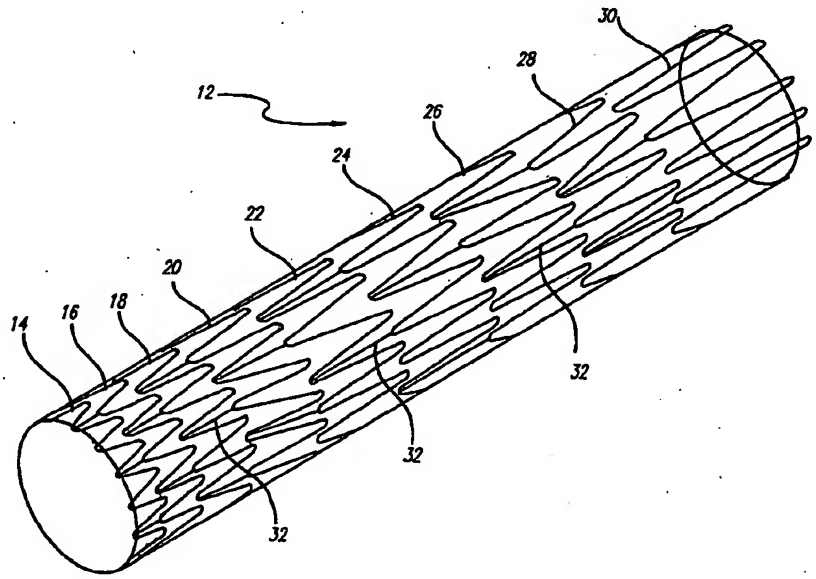

(57) Abstract

A stent (12) for use in a non-uniform deployment site such as in a tapered or bifurcated artery or in an ostial region. The stent (12) has a non-uniform structure selected to accommodate the non-uniformities inherent in the particular diseased area which it is intended to support. Non-uniformities can include differentiation in terms of its expansion ratio, radial strength, coverage and longitudinal flexibility.

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Description

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STENT HAVING NON-UNIFORM STRUCTURE

BACKGROUND OF THE INVENTION

The present invention generally relates to intravascular stents and more particularly, pertains to specialized stent configurations for the treatment of vascular disease within non-uniform vessels such as, for example, a tapered artery, or at the ostium or bifurcation of an artery.

Stents or expandable grafts are implanted in a variety of body lumens in an effort to maintain their patency. These devices typically are intraluminally implanted by use of a catheter which is inserted at an easily accessible location and then advanced to the deployment site. The stent initially is maintained in a radially compressed or collapsed state to enable it to be maneuvered through the lumen. Once in position, the stent is deployed which, depending upon its construction, is achieved either automatically by, for example, removing a restraint, or actively by, for example, the inflation of a balloon about which the stent is carried on the catheter.

Intravascular stents currently in use typically are designed to expand or to be expanded within a diseased vessel to a given nominal diameter that is constant along the entire length of the stent. The stent also typically is uniform along its entire length in terms of its radial strength, its longitudinal flexibility and its coverage, i.e., the actual area of stent material defining the surface of the deployed stent relative to the area of vessel covered thereby. Most blood vessels, however, are not of constant diameter, exhibiting either a natural taper or a narrowing, particularly near bifurcations. Blood vessels may be abruptly tapered over short lengths (less than 20mm), as in the carotid arteries, or gradually tapered over long lengths (greater than 20mm), as in the iliac arteries. Examples of bifurcation sites in the human circulatory system include the vascular profile where the external and internal carotid arteries branch out from the common carotid artery. The common carotid

artery is 7-9 mm in diameter while the internal carotid artery is 4-6 mm in diameter. In the event disease is present at such junction, a stent deployed therein must accommodate a 3-5 mm diameter change over a length of about 20-30 mm. Another example involves the stenting of the renal arteries. In order to cover the entire ostial area, it is necessary for the stent to conform to the interior of the renal artery and to flare into the significantly larger aorta. Moreover, the lesions present at the ostium are typically hard and calcified requiring the stent to possess greater strength in that specific region. Similar requirements arise in the treatment of ostial disease at the bifurcation in native coronary arteries or bypass grafts and aorta-ostial disease in the peripheral (e.g., carotid, renal and iliac) arteries. Non-uniformities also may be present by virtue of a curved or tortuous configuration of the blood vessel at the diseased site.

By fitting conventionally configured stents, i.e., stents of uniform shape and diameter, to such sites, a number of problems arise. In the event such stent is fitted to a tapered section of artery, either the artery is forced into an unnatural shape, or the stent must somehow become distorted during its deployment. By forcing the artery into an unnatural shape, certain sections of the tissue are caused to be overextended or other sections to be undersupported. Steps taken in an effort to non-uniformly expand a uniformly constructed stent have the effect of imparting undesired non-uniform characteristics to the device such as non-uniform radial strength, flexibility, and coverage. Another potential side effect associated with the use of a stent of uniform construction is that its deployment in a tortuous segment of vasculature would cause an undesirable straightening of such segment.

A stent therefore is needed with which a non-uniform vessel may be uniformly supported to provide consistency in terms of coverage, radial strength, and longitudinal flexibility along its entire length. Alternatively, a stent is needed that is capable of providing specific variations in terms of coverage, radial strength,

and longitudinal flexibility at certain locations along its length, in order to accommodate varying needs along the length of a particular vessel.

SUMMARY OF THE INVENTION

A stent of the present invention may be constructed so as to provide uniform coverage, uniform radial strength and/or uniform longitudinal flexibility to a non-uniformly shaped deployment site such as a vessel that is tapered or bifurcated. Alternatively, such stent may be constructed to accommodate non-uniform requirements of a particular site, wherein specific variations in flexibility, radial strength or coverage are required at specific locations along such stent.

The desired functional differentiation is achieved with a stent that is structurally differentiated in a preselected manner. Dimensional or geometric differentiation, or both dimensional and geometric differentiation, are relied upon to impart the desired variations of functional characteristics to a particular stent. Such structural differentiation may be gradual or abrupt and may include several different type of differentiations along the length of the stent.

A stent of the present invention constructed for deployment in a tapered vessel has a gradually increasing expansion ratio along is length. Such differentiation may be achieved with an assembly of axially aligned rings each with a serpentine structure, wherein each repeating pattern of serpentines defines a single unit cell. By selecting the size of the unit cells in successive rings to be increasingly wider, an increased amount of material becomes available for expansion. Upon expansion, such stent assumes the tapered shape of a truncated cone to match the shape of the tapered artery. Despite its tapered shape, the stent nonetheless provides uniform coverage of the walls of the tapered vessel as well as exhibits uniform radial strength and longitudinal flexibility along its entire length. The stent may be alternatively constructed so as to expand into any of a variety of shapes or profiles

to fit a particular application. Geometric or dimensional as well as both geometric and dimensional variations of the unit cell may be employed to achieve such functional variation.

As a further alternative, a stent of the present invention may be non-uniformly constructed so as to attain a uniform diameter along its entire length while it exhibits preselected variations of coverage, radial strength, or longitudinal flexibility along its length. This is achievable by, for example, varying the thickness of the serpentine elements while the width of each serpentine element is held constant, or by varying the number of unit cells in certain serpentine elements. A similar result can be achieved by simultaneously varying the dimensions (i.e., strut width and/or thickness of the unit cell), or the geometry, or both the dimensions and the geometry of the individual unit cells.

These and other features and advantages of the present invention will become apparent from the following detailed description of a preferred embodiment which, when taken in conjunction with the accompanying drawings, illustrates by way of example the principles of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

FIGURE 1 is a greatly enlarged plan view of a longitudinally severed and flattened stent of the present invention, shown in the predeployed state.

FIG. 2 is a perspective view of the stent shown in FIG. 1, also in the predeployed state.

FIG. 3 is a greatly enlarged plan view of the longitudinally severed and flattened stent of FIG. 1, shown in the deployed state.

FIG. 4 is a perspective view of the stent shown in FIG. 3, also in the deployed state.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Stents of the present invention are specifically constructed for particular deployment sites and thereby overcome the shortcomings inherent in attempting to fit a uniform stent to a non-uniform site. The non-uniformity of the site may include a taper, a bifurcation, an ostium, or any other variation in terms of dimensions or support requirements. The stent is maneuvered into place in the conventional manner, such as by a catheter about which it is carried while in its collapsed state. Once in position, the stent is expanded such as by the inflation of one or more balloons, or in the case of self expanding stents, a confining sheath is removed to allow the stent to expand automatically. Subsequent withdrawal of the catheter and associated deployment devices leaves the stent in place to maintain the patency of the vessel.

By providing a tapered stent for deployment within a tapered artery, uniform coverage, uniform radial strength and uniform stiffness nonetheless may be achieved along the entire length of the stent. Alternatively, the versatility of the system of the present invention allows a non-uniform stent to be constructed that imparts enhanced coverage, strength or stiffness at preselected locations so as to, for example, provide the needed support requirements in a diseased ostium.

FIG.1 illustrates stent 12 incorporating features of the present invention and more specifically, a stent for deployment in a tapered artery. The stent typically is tubular in its overall shape, however, the drawing shows the stent in a longitudinally severed and flattened state in order to clearly display its structure. The stent structure generally consists of a series of circumferentially extending serpentine

elements (14, 16,...30) that are interconnected by links 32 extending between adjacent serpentine elements. Each of the serpentine elements may be characterized as being made up of a number of individual unit cells 34, wherein each such cell consists of link 32 attached to two adjacent U- or V-shaped ribs 36,38. In the embodiment illustrated, a total of four unit cells define each serpentine element. Adjacent serpentine elements are arranged such that the respective series of apexes are in phase, and in longitudinal alignment with one another. All links extend from the same side of the serpentine elements. In the embodiment illustrated, all links extend between the left edges of the individual serpentine element.

In the embodiment illustrated in FIG. 1, each serpentine element is differentiated relative to the adjacent serpentine elements in terms of the width of the serpentine pattern, i.e., the length of each rib element as well as of each link element. In the particular embodiment shown, each successive serpentine element is progressively wider than the previous element, consequently, the rib and link elements of the respective unit cells are longer. The number of unit cells in each serpentine element, however, remains unchanged, as does the thickness and width of all of the rib and spine elements.

FIG. 2 is a perspective view of stent 12 as it actually appears in use prior to deployment. The overall tubular structure is of uniform diameter and each of the serpentine elements extend about the entire circumference of the device. The individual serpentine elements are recognizable as rings while the individual links 32 extend only between adjacent rings. The diameter of the stent is selected to be sufficiently small to allow passage through a patient's vasculature to the deployment site.

FIG. 3 illustrates the stent shown in FIGS. 1 and 2 in its deployed state. The device again is shown longitudinally severed and flattened in order to more clearly display its structure. As is clearly visible, the expansion of the device results in a tapered shape wherein the wider serpentine elements shown towards the right side

of the device expand to a greater extent than the narrower serpentine elements shown toward the left side of the device. Such expansion results in a truncated cone shape when shown in perspective as in FIG. 4. Each of U- or V-shaped ribs 36,38 assumes a wider, more open angle while the links 32 remain essentially stationary and aligned. The deformation and expansion of the ribs provides for the increase in the diameter of the device, yet the overall length of the stent remains essentially unchanged during deployment of the stent, since the links connect only adjacent rings to each other. This is a highly desirable characteristic of a stent, as any shortening would not only reduce the total area supported by the device, but also could cause trauma to the surrounding tissue during deployment. Additionally, because more stent material is present in the larger diameter rings by virtue of the presence of the same number of longer ribs, the radial strength, coverage and stiffness of the stent remains fairly constant along its entire length.

While the figures illustrate the structure of a single embodiment of the present invention and the distortion it undergoes during deployment, it should be understood that vast numbers of variations are possible to enable a stent to be tailored to the specific requirements of a particular application. By varying or differentiating the geometry of the stent's structure or of the individual unit cells, a commensurate variation or differentiation in function is achieved. Functional differentiation also is achievable by varying the thickness or width of the individual ribs. Desired functional differences also are achievable by varying the number of unit cells either gradually along the length of the stent or in isolated locations thereon. Both the number of unit cells, the geometry of such cells, and the dimensions of such cells may be varied in any combination to achieve a particular functional effect.

The above-described variables can be selected such that the resulting stent is specifically tailored to a very specific anatomical requirement, be it the taper, bifurcation twist, or ostium of a vessel. In addition to fitting the dimensional

requirements of a particular non-uniformity in the anatomy, the same variables can be selected such that the resulting stent is specifically tailored to provide a desired radial strength, longitudinal flexibility, or coverage differentiation.

A stent of the present invention may be constructed using any number of well-known techniques. Preferably, a stainless steel tube is laser cut with the desired stent pattern as is known in the art. Digital angiography and advanced computing algorithms are valuable tools that are readily useable to create a structurally differentiated stent that conforms to the natural profile of a vessel upon deployment. Chemical etching or electro-polishing techniques, which are well known, subsequently may be used to selectively vary the wall thickness of such stent.

Deployment maybe achieved by shaped balloons for balloon-expandable stents whereby a tapered balloon is used to expand a tapered stent within a tapered vessel. Alternatively, multiple balloons of varying size may be used to achieve a similar effect, as may the tapered section of an over-sized balloon. As a further alternative, the stent may be constructed to be self-expanding by any of various techniques well known in the art. Deployment of a self-expanding stent can be achieved by subjecting the collapsed stent which is constructed of a shape memory alloy, to certain temperatures which cause it to expand. A stent constructed of elastic material may be forcefully collapsed and constrained within a sheath. Removal of the sheath allows the stent to automatically expand.

Balloon expandable stents may be manufactured from any number of ductile metals and alloys including, stainless steel, tantalum, and platinum-iridium alloys, either coated or uncoated. Self-expanding stents are constructed of shape memory or superelastic materials or alloys such as NiTi alloys, including Nitinol, and Cu-Zn alloys.

While a particular form of the invention has been illustrated and described, it also will be apparent to those skilled in the art that various modifications can be

made without departing from the spirit and scope of the invention. Accordingly, it is not intended that the invention be limited except by the appended claims.

Claims

WHAT IS CLAIMED IS:

1. A stent for supporting a vascular region having non-uniform support requirements, comprising:

a structure, differentiated so as to provide support in a non-uniform manner to accommodate said non-uniform support requirements.

2. The stent of claim 1, wherein said structure is differentiated so as to expand to different diameters along its length while exhibiting substantially constant radial strength along its length.

3. The stent of claim 1, wherein said structure is differentiated to provide a constant amount of coverage along its length.

4. The stent of claim 3, wherein said structure is differentiated so as to expand to a truncated cone shape in order to accommodate a similarly tapered artery.

5. The stent of claim 1, wherein said structure is differentiated so as to expand to a constant diameter along its length while exhibiting a preselected variation in radial strength along its length.

6. The stent of claim 1, wherein said structure is differentiated so as to expand to a constant diameter along its length while providing a preselected variation in coverage along its length.

7. The stent of claim 1, wherein said structure is comprised of an assembly of unit cells and wherein the dimensions of said individual unit cells and the number of said unit cells vary along the length of said stent.

8. The stent of claim 1, wherein said structure is comprised of an assembly of unit cells and wherein the geometry of individual cells vary along the length of said stent.

9. The stent of claim 8, wherein said unit cells additionally vary with respect to their dimensions.

10. The stent of claim 1, wherein said structure is formed by laser cutting voids into a tube.

11. The stent of claim 1, wherein said structure is formed of wire.

12. A stent for supporting a vascular region having a tapered shape, comprising:

a structure, differentiated so as to expand to said tapered shape while providing constant support along it length.

13. The stent of claim 12 comprising, an assembly of expandable rings and wherein the width of each successive ring is increased.

14. The stent of claim 13, wherein each ring comprises a serpentine structure.

15. The stent of claim 14, wherein each of said serpentine structures comprises a plurality of repeating unit cells, each unit cell consisting of a longitudinally oriented link from which two deformable generally U- or V-shaped ribs extend.

16. The stent of claim 15, wherein the lengths of said link and said ribs for each unit cell are selected to impart a preselected diameter to said stent upon expansion.

17. The stent of claim 12, wherein said structure is formed by laser cutting voids into a tube.

18. The stent of claim 12, wherein said structure is formed of wire.

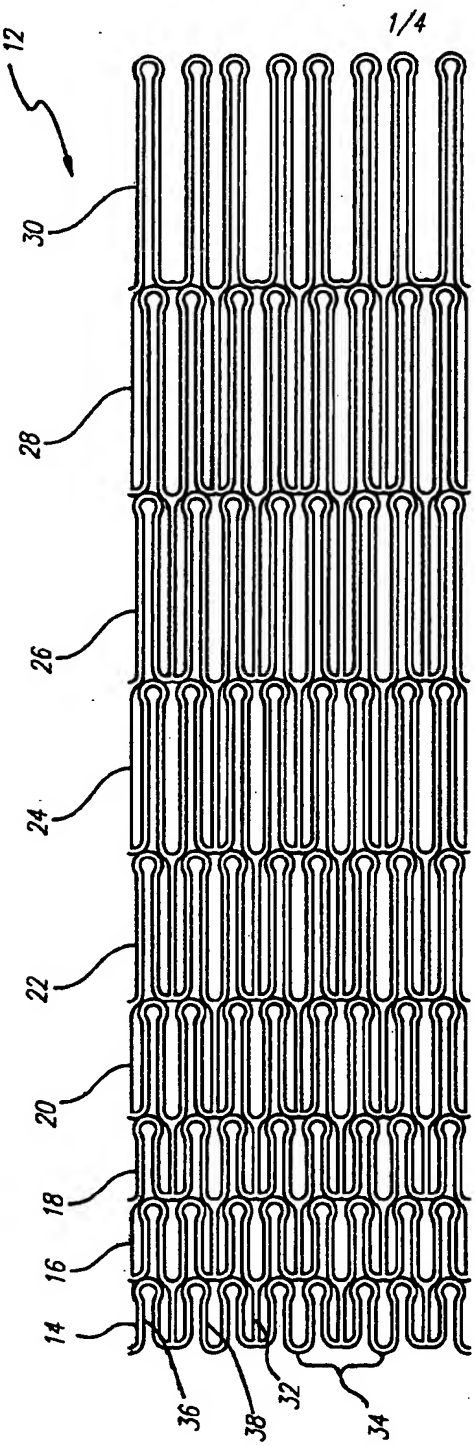

FIG. 1

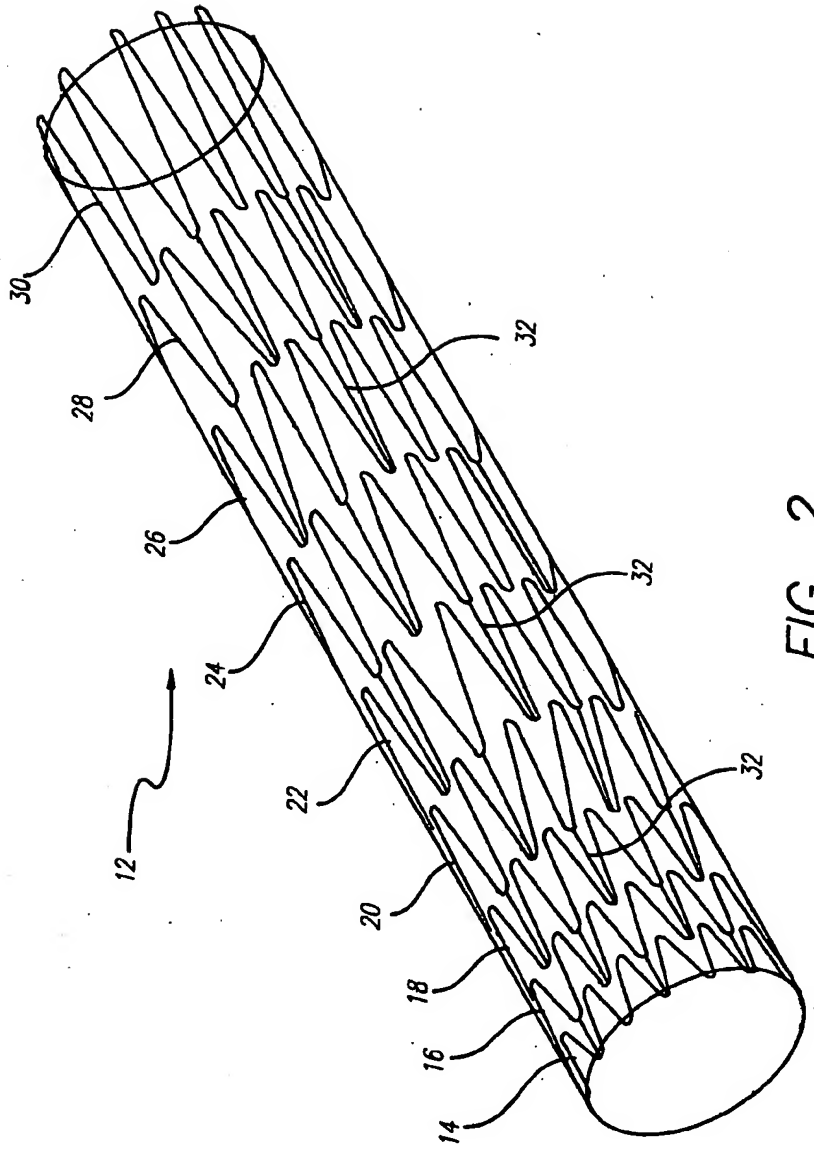

FIG. 2

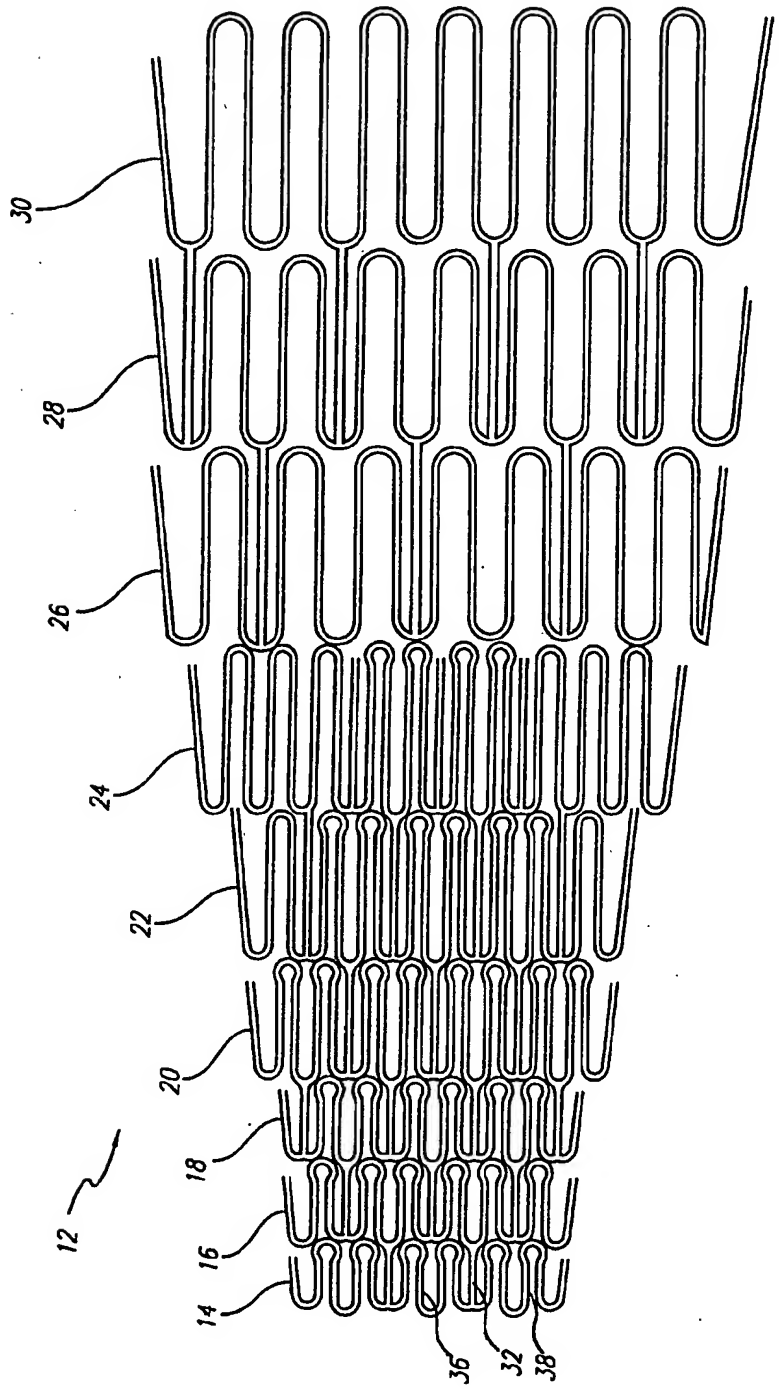

FIG. 3

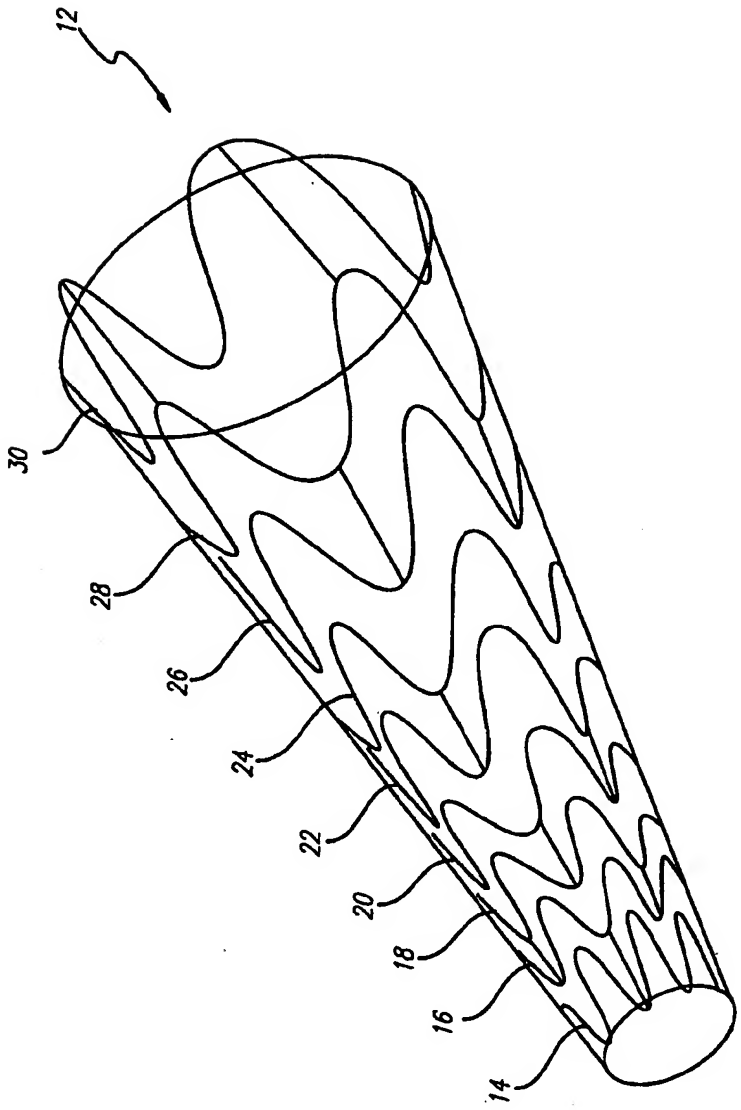

FIG. 4

INTERNATIONAL SEARCH REPORT

Intern nal Application No
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A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F2/06

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Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

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C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 617 878 A (TAHERI SYDE A) 8 April 1997 (1997-04-08) column 1, line 64 -column 2, line 20 column 4, line 47 -column 6, line 3 claims 1,3-7; figures 13-15	1-4, 7-10,12, 13,16,17
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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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INTERNATIONAL SEARCH REPORT

information on patent family members

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